K003006

SECTION 2. 510(K) SUMMARY

OCT 2 7 2000

P.O. Box 12888
Reading, PA 19612

ARROW INTERNATIONAL

Research/Engineering
2400 Bernville Road
Reading, PA 19605

(610) 378-0131
FAX: (610) 478-3188

Submitter

Arrow International
2400 Bernville Road
Reading, PA 19605

Contact person:

Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Phone: (610) 478-3137
Fax: (610) 478-3172
E-mail: tom.nickel@arrowintl.com

Date summary prepared: 09/21/00

Device trade name: PICC Two-lumen Peripherally Inserted Central Catheter Kit with Blue FlexTip® Catheter and Integral Needle Protection

Device common name: Peripherally inserted central venous catheter

Device classification name: Class II at 21 CFR 880.5200, Catheter, Intravascular, short term

Legally marketed devices to which the device is substantially equivalent:

- K930129: Arrow PICC Peripherally Inserted Central catheterization kit
- K990236: PROTECTIV™ Safety Introducer System

Description of device:

The proposed device is a sharps-protected version of the Arrow PICC Catheterization Kit. It contains a 14 Ga x 1 ¼" Peel-away-catheter-over-15 Ga-needle assembly with an integral, passive needle protection feature. A 5 Fr x 22 ½" catheter is inserted through the peel-away introducer catheter-over-needle assembly for venous access to the central circulation through a peripheral vein. It offers an alternative method of intravenous therapy for select adult and pediatric patients.

The catheterization kit components are configured in a High Impact Polystyrene (HIPS) tray and sealed with a Tyvek® lidstock, and sterilized.

Intended use of the device:

A Peripherally Inserted Central Catheter permits venous access to the central circulation through a peripheral vein. It offers an alternative method of intravenous therapy for select adult and pediatric patients. The Peel-Away Introducer over Needle Assembly permits venous access for catheter introduction and is intended to help minimize the risk of sharps injuries during use.

Technological characteristics:

The proposed device has the same technological characteristics as the Arrow predicate device.

Performance tests:

The following performance tests are included in the submission:

1. Clinical simulation
2. Deactivation force of safety feature
3. Tensile
4. Corrosion.

Conclusions:

The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2000

Mr. Thomas D. Nickel
Vice President of Regulatory Affairs & Quality Assurance
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K003006
Trade Name: Two-Lumen PICC With Blue FlexTip Catheter and Integral Needle Protection
Regulatory Class: II
Product Code: LJT
Dated: September 22, 2000
Received: September 26, 2000

Dear Mr. Nickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 12. INDICATIONS FOR USE STATEMENT

510(k) Number K003006

Device Name: PICC Two-Lumen Peripherally Inserted Central Catheter Kit with Blue FlexTip® Catheter and Integral Needle Protection.

Indications For Use: A Peripherally Inserted Central Catheter permits venous access to the central circulation through a peripheral vein. It offers an alternative method of intravenous therapy for select adult and pediatric patients.

The Peel-Away Introducer over Needle Assembly permits venous access for catheter introduction and is intended to help minimize the risk of sharps injuries during use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control
and General Hospital Devices
510(k) Number K003006